



EC-CERTIFICATE

(Full quality assurance system)



This is to certify that the company

MicroVention, Inc.

1311 Valencia Ave.
Tustin, CA, 92780
United States of America

has implemented and maintains a full quality assurance system which applies to the products at every stage from design to final controls.

Through an audit, documented in a report, performed by DQS Medizinprodukte GmbH, it was verified that the management system fulfills the requirements of

Annex II – excluding Section 4 of Council Directive 93/42/EEC concerning medical devices

with respect to the following medical devices:

Embolization Prostheses and Accessories, Intravascular Access Devices (Occlusion Balloon Catheters, Guiding and Aspiration Catheters, Microcatheters and Guidewires) and Accessories, Stents, Clot and Foreign Body Retrieval Devices, Liquid Embolic System, Embolic Protection System, Aneurysm Embolization Device, Microspheres, Aspiration Devices, and Detachment Controller Units as listed in Annex.

The manufacturer is subject to surveillance according to Annex II, Section 5. The CE marking with the Notified Body Identification Number (0297) may be affixed on the devices listed in the certificate. An EC Design Examination Certificate according to Annex II, Section 4 is required for class III devices covered by this certificate. The certificate is in the case of class I(s) devices (I(s) = class I products placed on the market in sterile conditions) limited to the aspects of manufacture concerned with securing and maintaining sterile conditions. The certificate is in the case of class I(m) devices (I(m) = class I devices with a measuring function) limited to the aspects of manufacture concerned with the conformity of the products with the metrological requirements.

Certificate registration no. 411133 MR2

Certificate unique ID 170771828

Effective date 2020-09-11

Expiry date 2024-05-26

Frankfurt am Main 2020-09-11

DQS Medizinprodukte GmbH

Sigrid Uhlemann
Managing Director

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Head of Certification Body

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DQS Medizinprodukte GmbH is a Notified Body according to Council Directive 93/42/EEC concerning medical devices with the Identification Number 0297.



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Production Sites:

1.
MicroVention, Inc.
35 Enterprise,
Aliso Viejo, CA 92656
United States of America
2.
MicroVention, Inc.
1311 Valencia Ave.
Tustin, CA 92780
United States of America
3.
MicroVention Costa Rica, S.R.L.
Zona Franca Coyol
Alajuela,
Costa Rica



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Device Groups:	Device Family:	Devices:	Risk Class	Production Site
Embolization Prothese	MicroPlex Coil System (MCS) & HydroCoil Embolic System (HES) with V-Trak Delivery System	MicroPlex 10 Platinum Coil System (MCS) Endovascular Embolization Coil	III	1,2,3
		- Cosmos10		
		- HyperSoft 3D		
		- HyperSoft Helical		
	MicroPlex 18 Platinum Coil System (MCS) Endovascular Embolization Coil	- Helical 10	III	1,2,3
		- VFC		
		- Compass 10		
		- Complex 10		
	HydroCoil 10 Embolic System (HES) Endovascular Embolization Coil	- Cosmos 18	III	1,2,3
		- Helical 18		
		- Compass 18		
		- Complex 18		
	HydroCoil 18 Embolic System (HES) Endovascular Embolization Coil	HydroCoil 10 Embolic System (HES) Endovascular Embolization Coil	III	1,2,3
		- HydroFrame 10		
		- HydroSoft Helical		
		- HydroSoft 3D		
	AZUR® Peripheral Coil System	- HydroFill	III	1,2,3
		HydroCoil 18 Embolic System (HES) Endovascular Embolization Coil		
		- HydroFrame 18		
		AZUR® HydroCoil Detachable Embolization Coils 18 & 35	IIb	1,2,3
	AZUR® Framing Detachable Coils 18 & 35	AZUR® HydroCoil Pushable Embolization Coils 18 & 35		
		AZUR® Framing Detachable Coils 18 & 35		
		AZUR® Injectable Coil System 18 & 35		
	AZUR Detachable 18	AZUR Detachable 18	IIb	1,2,3
		AZUR PURE Pushable Coil System 18 & 35		
		AZUR CX Detachable 18 & 35		
		AZUR Vascular Plug		

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Detachment Controller Units		V-Grip® Detachment Controller	Ila	1,2
		V-Grip® PLUS Detachment Controller	Ila	1,2
		WEB Detachment Controller	Ila	1,2
		AZUR® Detachment Controller	Ila	1,2
Intravascular Access Devices (Occlusion Balloon Catheters, Guiding and Aspiration Catheters, Microcatheters and Guidewires)		Traxcess® 14 Guidewire	III	1,2
		Traxcess® 14 EX Guidewire	III	1,2
		Traxcess® 14 SELECT Guidewire	III	1,2
		Traxcess® 7 Mini Guidewire	III	1,2
		Traxcess® 7 Mini XSoft Guidewire	III	1,2
		Traxcess® Docking Wire	Ila	1,2
		Chaperon® Guiding Catheter System	III	2
		Headway® 17 Advanced Soft Microcatheter	III	1,2,3
		Headway® 17 Advanced Microcatheter	III	1,2,3
		Headway® 21 Microcatheter	III	1,2,3
		Headway® 27 Microcatheter	III	1,2,3
		Headway Duo Microcatheter	III	1,2,3
		Scepter C™ Occlusion Balloon Catheter	III	1,2,3
		Scepter XC™ Occlusion Balloon Catheter	III	1,2,3
		Scepter Mini™ Occlusion Balloon Catheter	III	1,2,3
		SOFIA™ Distal Access Catheter	III	1,2,3
		SOFIA™ Select Catheter	III	1,2,3
		SOFIA™ PLUS Catheter	III	1,2,3
		SOFIA™ Flow PLUS Catheter	III	1,2,3
		SOFIA™ Guiding Catheter	III	1,2,3
		SOFIA™ Flow Catheter	III	1,2,3
		SOFIA® EX Catheter	III	1,2,3
		KANSHAS Drug Coated Balloon	III	1
		VIA™ 17 Microcatheter	III	1,2
		VIA™ 21 Microcatheter	III	1,2
		VIA™ 27 Microcatheter	III	1,2
		VIA™ 33 Microcatheter	III	1,2
		Wedge Microcatheter	III	1,2,3
		PG Pro Microcatheter	Ila	1,2,3

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Stents		LVIS™ Intraluminal Support Device	III	1,2,3
		LVIS™ Jr. Intraluminal Support Device	III	1,2,3
		LVIS™ EVO™ Intraluminal Support Device	III	1,2,3
		LVIS™ X™ Intraluminal Support Device	III	1,2,3
		LVIS™ Jr. X™ Intraluminal Support Device	III	1,2,3
		LVIS™ EVO™ X™ Intraluminal Support Device	III	1,2,3
		FRED® Flow Re-Direction Endoluminal Device	III	1,2,3
		FRED Jr.® Flow Re-Direction Endoluminal Device	III	1,2,3
		FRED X® Flow Re-Direction Endoluminal Devices	III	1,2,3
		CASPER™ RX Carotid Artery Stent System	III	1,2,3
Peripheral Vascular Stent System		Roadsaver Carotid Artery Stent System	III	1,2,3
		RENZAN™ Peripheral Vascular Stent System	IIb	1,2,3
Clot Retriever		ERIC™ Retrieval Device	III	1,2,3
Liquid Embolic System		PHIL™ Liquid Embolic System	III	1,2
Microspheres		HydroPearl Microspheres	IIb	1,2
		LifePearl Microspheres	III	1,2
		BioPearl® Microspheres	III	1



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Embolic Protection Device (EPS)		Empro Embolic Protection System	III	1,3
		Nanoparasol Embolic Protection System	III	1,3
Aneurysm Embolization Device		WEB™ Aneurysm Embolization System	III	1,2
Aspiration Kit		Aspiration Tubing Kit	Is	1,2
		Aspiration Syringe Kit	Is	1,2
BOBBY™ Balloon Guide Catheter		BOBBY™ Balloon Guide Catheter	III	1,2